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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/763,148

01/21/2004

William W. Van Osdol

ARC

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10/30/2006

ALZ5121USANP/IR3349

EXAMINER

JACOB, MARY C

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ART UNIT

PAPER NUMBER

2123

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,148

Applicant(s)

VAN OSDOL ET AL.

Examiner

Mary C. Jacob

Art Unit

2123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-6 have been presented for examination.
2. The drawings, filed 6/28/04, have been received.

Drawings

3. The drawings are objected to because Figure 4 is not mentioned in the specification and Figure 7, which is mentioned in the specification on page 16, line 13, page 17, line 23 and page 18, line 13, is not in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 3 is objected to because of the following informalities: the formula at line 15 contains $c_1^i = c_1^i(x,t)$. Since the equation in the specification (page 7, line 5) does not use the "" after c_1^i , it appears that the use of "" may be a typographical error.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: in claim 1, the steps for "modeling nonlinear diffusion of a multicomponent system in heterogeneous media; in claim 4, the steps for "modeling nonlinear diffusion of a drug and a permeation enhancer in a heterogeneous transdermal system.

8. Claims 2 and 5 recite the limitation "the step of applying a Lagrange multiplier method" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims

9. Claims 2 and 5 recite the limitation "the nonlinear partition coefficient" in line 2.

There is insufficient antecedent basis for this limitation in the claims.

10. Claims 3 and 6 recite the limitation "the diffusion coefficients". There is insufficient antecedent basis for these limitations in the claims.

11. Claims 3 and 6 recite $c_1^i = c_1^i(x, t)$ and $c_2^i = c_2^i(x, t)$, but do not recite what these limitations are directed to.

12. Claim 5 recites the limitation "the multicomponent system" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Interpretation

13. Office personnel are to give claims their "**broadest reasonable interpretation**" in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Limitations appearing in the specification but not recited in the claim are not read into the claim. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969). See *also *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) ("During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow") The reason is simply that during patent prosecution when claims can be amended, ambiguities should be recognized, scope and breadth of language explored, and clarification imposed An essential purpose of patent examination is to fashion claims that are precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed, as much as possible, during the administrative process.

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14. Claims 3 and 6 do not indicate what the meaning of $c_1^i = c_1^i(x,t)$ and $c_2^i = c_2^i(x,t)$ are. From the specification, page 13, lines 21-23, these terms were interpreted to be concentrations.

15. Claim 5 recites "one or more components included in the multicomponent system", however it is unclear what the "multicomponent system" is or what the "components" are. Since Claim 5 depends on Claim 4, and in accordance with the specification (page 13, lines 21-23), it was concluded that the "multicomponent system" is directed to the "transdermal system" and the "components" are the "drug" and the "permeation enhancer".

Claim Rejections - 35 USC § 101

16. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

17. Claims 1-6 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are a recitation of abstract ideas and mathematical algorithms and fail to recite a concrete, useful or tangible result.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Filo et al ("A Free-Boundary Problem in Dermal Drug Delivery", SIAM Journal on Mathematical Analysis, 'Online'! Vol. 33, no. 6, pages 1-21, 2001).

20. Filo et al teaches: (claims 1, 2) a method for modeling nonlinear diffusion of a multicomponent system in heterogeneous media (Abstract; pages 2-4); (claim 2) applying a Lagrange multiplier method for treating the nonlinear partition coefficient of one or more components included in the multicomponent system (page 2, equations 1.7-1.9 and descriptions).

21. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Farhadieh et al (US Patent 5,164,189).

22. Farhadieh et al teaches a method for modeling nonlinear diffusion of a drug and a permeation enhancer in a heterogeneous transdermal system (column 1, lines 39-42; column 7, lines 53-56; column 8, lines 8-12; column 14, lines 15-27, 39-68; column 15, lines 6-16, 50-62; column 16, lines 3-7, 21-68; Figures 2 and 3).

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farhadieh et al in view of Filo et al.

25. Farhadieh et al teaches a method for modeling nonlinear diffusion of a drug and a permeation enhancer in a heterogeneous transdermal system.

26. Farhadieh et al does not expressly teach applying a Lagrange multiplier method for treating the nonlinear partition coefficient of one or more components included in the multicomponent system.

27. Filo et al teaches a free-boundary problem in a multicomponent domain, motivated by the mathematical modeling of dermal and transdermal drug delivery where

the multilayered skin model is considered (Abstract) wherein a Lagrange multiplier method is applied for treating the nonlinear partition coefficient of one or more components included in the multicomponent system (page 2, equations 1.7-1.9 and descriptions).

28. Farhadieh et al and Filo et al are analogous art since they are both directed to the modeling of nonlinear diffusion of a drug in a heterogeneous transdermal system.

29. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modeling of the nonlinear diffusion of a drug and a permeation enhancer in a heterogeneous transdermal system as taught in Farhadieh et al to further include applying a Lagrange multiplier method for treating the nonlinear partition coefficient of one or more components included in the multicomponent system as taught in Filo et al since Filo et al teaches a free-boundary problem in a multicomponent domain, motivated by the mathematical modeling of dermal and transdermal drug delivery where the multilayered skin model is considered (Abstract) and since both Farhadieh et al and Filo et al are directed to the modeling of the diffusion of a drug from a transdermal patch through the skin.

Conclusion

30. Any indication of allowability of the claims rejected under 35 USC 112 2nd paragraph, but not on prior art is being held in abeyance pending the manner in which applicant amends or responds to this rejection under 35 USC 112 2nd paragraph.

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

32. Banerjee et al ("Finite Element Model of Antibody Penetration in a Prevascular Tumor Module Embedded in Normal Tissue", Journal of Controlled Release, 74, pages 193-202, 2001) teaches a pharmacokinetic model for monoclonal antibodies to aid in investigating protocols for targeting small primary tumors or sites of metastatic disease.

33. Grass et al (US Patent 6,647,358) teaches a pharmacokinetic-based design and selection tool and methods for predicting absorption of an administered compound of interest.

34. Loper et al (US Patent 4,797,284) teaches a multilaminate transdermal drug delivery system containing only dissolved drug in the drug reservoir is described.

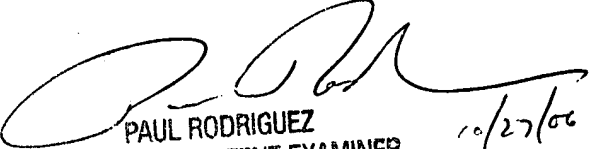
35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary C. Jacob whose telephone number is 571-272-6249. The examiner can normally be reached on M-F 7AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached on 571-272-3753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mary C. Jacob
Examiner
AU2123

MCJ
10/26/06


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10/27/06